United States Department of Agriculture
Agricultural Marketing Service
Science & Technology
Monitoring Programs Office
8609 Sudley Rd., Ste. 206
Manassas, VA 20110

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TO: See Distribution List

FROM: Martha Lamont, Director
Monitoring Programs Office

SUBJECT: Microbiological Data Program Plan, July through December 2008

This Program Plan serves as the current Statement of Work for the period July 1, 2008 through December 31, 2008, for each State participating in the Microbiological Data Program (MDP). This document also stipulates work assignments for the Federal facility participating in MDP.

I. ADMINISTRATIVE UPDATES

A. Program Status: At the FY 2009 House Appropriations Hearing, a member of the House expressed interest in working with the Agency to continue operating the MDP program**.** In response, the Agency has instructed MDP to issue plans to continue program operations in fiscal year (FY) 2009. The budget for FY 2009 is likely to be at the same level as in FY 2008 ($4.8 million); therefore, beginning January 2009, MDP may need to make adjustments (e.g., decrease number of samples collected and analyzed) in order to absorb rising operational costs.

B. Personnel: MDP has issued a recruitment announcement to hire a Microbiologist to replace Dr. Shanker Reddy, who has taken a position with the USDA Food Safety and Inspection Service. Terry Councell and John Punzi have taken over Dr. Reddy's responsibilities while the position is vacant. Program participants are reminded to keep MDP management informed of any critical equipment purchases, staffing issues, or expected increases in rent or sample turn-around-time (e.g., due to laboratory or office renovation/relocation). This information is required under the terms of MDP Cooperative Agreements (Section II, Responsibilities) between USDA and participating States.

C. Sample Origin Information: MDP began collecting sample origin information , effective February 1, 2008. Information collected includes grower, packer, distributor, country of origin, collection facility name, and lot number/product code.

D. Data Reporting: State and Federal program participants are reminded that routine sample results, including any in-house confirmations, must be reported within 60 days of receipt of the last sample of each batch. This requirement is reflected in Standard Operating Procedure (SOP) MDP-DATA-01, subsection 5.5.2. In response to requirements of the Office of Management and Budget (OMB) Program Assessment

Rating Tool (PART), MPO will issue letters of warning to laboratories with any backlog exceeding 60 days, unless the laboratory has provided the required notification to MPO.

E. Summary Status: The 2007 MDP Progress Update and Data Summary was released via the Website in March 2008. The 2002-2006 MDP Progress Update and Data Summaries are also available on the MDP website at **http://www.ams.usda.gov/mdp**.

F. Financial/Cooperative Agreements: Cooperative agreements for fiscal year (FY) 2008, originally set to end on September 30, 2008 have been amended to extend the ending date to December 31, 2008. The amendments were issued to ensure that sampling and testing would not be disrupted between fiscal years.

G. MDP Program Meetings: A Technical Meeting was held January 29-30, 2008 in New Orleans, Louisiana. Attendees included MDP Technical Program Managers (TPMs) and Quality Assurance Officers (QAOs) from all MDP participating States and MPO staff. Program planning, technical, and quality assurance (QA) issues were addressed and are reflected in the Program Plan.

H. Electronic Transfer of Data:

RDE Version Upgrades: During March/April 2008, MPO made several real-time fixes to RDE SQL Stored Procedures and the database structure to fix identified data entry glitches, including modifications to allow entry of a numeric result greater than 1 million, to eliminate the inadvertent creation of associated mPCR records for tests other then *E.coli*, and to streamline the list of isolates shown on the Samples-to-Reference-Lab screen. With the next Web-RDE version upgrade, tentatively scheduled for June 2008, MPO plans to make password management more secure, increase the size of some text fields, and fix problems reported by laboratory users. With the next version upgrade to the RDE e-SIF system for laptops/palmtops, tentatively scheduled for September 2008, MPO plans to increase the size of the data entry screens, add a flag field to indicate if the SIF has already been exported for transmittal to MPO, and make the size of the text fields match the updated Web-RDE system. MPO maintains a Change Request Database to capture all problems identified and suggestions made regarding the RDE system.

II. PROGRAM SAMPLING AND TESTING UPDATES

A. Sampling: Shipping Charts are distributed quarterly to Sampling Managers by MPO. Draft shipping charts for calendar year 2008, 3rd and 4th Quarters, are attached to this document. Alfalfa sprouts, cantaloupe, bagged lettuce, spinach, and tomatoes will continue. Samples collected in Maryland will be sent to the Ohio laboratory (OH4) and those collected in Texas will be shipped to NSL (US4). Samples collected in California will be sent to the following MDP laboratories: alfalfa sprouts and bagged lettuce to Ohio (OH4), cantaloupes and tomatoes to NSL (US4), and spinach to Colorado (CO4). Samples from all other States will be sent to the laboratory for that collection State.

B. Testing: Alfalfa sprouts, cantaloupes, bagged lettuce, spinach, and tomatoes will continue. The Ohio laboratory (OH4) will analyze all samples collected by Ohio and Maryland as well as alfalfa sprouts and bagged lettuce collected by California. NSL (US4) will analyze all samples collected by Texas and cantaloupe and tomato samples collected by California. Colorado will analyze all samples collected by Colorado and

spinach collected by California. All other States will analyze samples collected in that State.

Target Microorganisms:

(1) *Escherichia coli* (*E. coli*): MDP laboratories will continue to test all samples for *E. coli* using the TEMPO® system. Method procedures are detailed in SOP MDP-MTH-01A [Enumeration of *Escherichia coli* in produce samples by TEMPO® EC (*E. coli*) Method, Original Version, 05/01/07].

(2) Coliform Count: All laboratories will capture total coliform bacteria for bagged lettuce and bagged spinach using the TEMPO® system. This method is specified in SOP MDP-MTH-01B [Enumeration of Coliform Bacteria in Produce Samples by TEMPO® CC (Coliform Count) System, Original Version, 05/01/07].

(3) TVC Count: All laboratories will capture TVC data for bagged lettuce and bagged spinach using the TEMPO® system. This method is specified in SOP MDP-MTH-01C [Enumeration of Total Viable Count (TVC) in Produce Samples by the TEMPO® TVC System, Original Version, 03/01/08].

(4) Pathogenic *E. coli*: All laboratories will continue to screen all samples for pathogenic *E. coli* according to SOP MDP-MTH-07 [Detection of Pathogenic *E. coli* in Fresh Produce by Multiplex PCR (mPCR) and Cultural Isolation and Identification, Revision 3, 05/01/07]. The mPCR assay tests for two types of pathogenic *E. coli*: (a) shiga toxin-producing *E. coli* (STEC) that carry genes coding for shiga toxins (Stx) 1 and 2 and (b) enterotoxigenic *E. coli* (ETEC) that carry genes coding for enterotoxins, heat labile (LT), and heat stable (ST) toxins.

(5) *Salmonella:* MDP laboratories will continue to screen all samples for *Salmonella* (presence or absence) by BAX®. Method procedures are detailed in SOP MDP-MTH-04 (Detection of *Salmonella* in Fresh Produce by BAX® PCR, Revision 2, 01/01/06). Presumptive positive samples are subjected to enrichment and isolation as described in SOP MDP- MTH-03A (Isolation and Identification of *Salmonella* from Fresh Produce using Cultural Methods, Revision 1, 01/01/06).

(6) *E. coli* O157:H7: MDP laboratories will continue to screen all samples for *E. coli* O157:H7 (presence or absence) by BAX®. Method procedures are detailed in SOP MDP-MTH-05 (Detection of *Escherichia coli* O157:H7 in Fresh Produce by BAX® PCR, Revision 2, 01/01/06). Presumptive positive samples are subjected to IMS procedures and cultural confirmation, as described in SOP MDP-MTH-06 (*Isolation and Identification of Escherichia coli* O157 by Immunomagnetic Separation (IMS) and Cultural Methods (Revision 3, 05/01/07).

(7) *Shigella:* MDP laboratories will continue to screen all samples for *Shigella* using realtime PCR. Method procedures are detailed in SOP MDP-MTH-08 [Detection of *Shigella* spp. in Fresh Produce by Realtime Polymerase Chain Reaction (rtPCR) and Cultural Isolation and Identification, Original Version, 03/01/08].

C. Quality Assurance:

Proficiency Testing Program: The next proficiency testing (PT) round will be introduced in July/August 2008. The test organism will be unknown to the laboratories. Each laboratory should perform all MDP tests on the samples provided.

Method Validation: A report detailing the successful method validation of *Shigella* testing by realtime PCR was issued in May 2008. All laboratories validated the method, including confirmatory steps, on bagged lettuce and alfalfa sprouts, commodities determined to be representative of the commodities in the program.

SOPs: The following new and revised SOPs and applicable attachments were issued February/March 2008:

- SOP MDP-LABOP-02: Sample Receipt, Elution, Preenrichment, and DNA Extraction, Rv. 09, 02/11/08
- SOP MDP-DATA-01: Record Keeping and Results Reporting, Rv. 04, 03/01/08
- SOP MDP-DATA-02: Data Storage and Archival (Revision 03, 03/01/08)
- SOP MDP-MTH-01C:Enumeration of Total Viable Count (TVC) in Produce Samples by the TEMPO® TVC System, Original Version, 03/01/08
- SOP MDP-MTH-08: Detection of *Shigella* spp. in Fresh Produce by Realtime Polymerase Chain Reaction (rtPCR) and Cultural Isolation and Identification, Original Version, 03/01/08
- SOP MDP-QA-02: Proficiency Test Samples, Rv. 02, 03/01/08
- SOP MDP-QA-03: Quality Assurance (QA) Controls, Rv. 04, 03/01/08

SOPs are posted to the MDP website at the time of distribution to program participants. Refer to: http://www.ams.usda.gov/mdp.

D. Archiving and Additional Testing:

Archival of Isolates: NSL (US4) serves as a centralized location for archival of isolates as well as a distribution center for isolates from MDP testing laboratories to the reference laboratories.

Additional Testing by Reference Laboratories: All target organisms are frozen in Microbank™ vials and shipped to NSL (US4). Vials are shipped by NSL (US4) to the FDA/Center for Veterinary Medicine (CVM) laboratory in Laurel, Maryland for antimicrobial resistance testing for inclusion in the National Antimicrobial Resistance Monitoring System (NARMS) and pulsed-field gel electrophoresis (PFGE) analysis for inclusion in PulseNet. *Salmonella* and *E. coli* O157 isolates are also serotyped by FDA/CVM. Pathogenic *E. coli* and *Shigella* isolates are shipped by NSL (US4) to Pennsylvania State University (PSU) for serotyping and testing for additional virulence attributes.

E. Transfer of Data: AMS transfers data to the Centers for Disease Control and Prevention (CDC) and FDA on a semi-annual basis. In addition, MDP data is given to USDA's Food Safety and Inspection Service (FSIS) and Agricultural Research Service (ARS). MDP data are available on request to MPO.